REMARKS/ARGUMENTS

By the foregoing amendment, independent claims 1 and 13 have been amended to clarify the claimed subject matter. No new matter has been added. Reconsideration is respectfully requested.

35 U.S.C. §112 Rejections

In the Office Action, claim 1 was objected to on grounds that reference to "said first blood vessel" lacked antecedent basis. This has been corrected by the foregoing amendment.

Also, in the Office action claim 1 was objected to on grounds that it is "unclear how the imaging transducer operates in regard to the catheter device, as there is no evident relationship between the two." By the foregoing amendment, claim 1 has been amended to further specify that the penetrator advances laterally from a side opening in the catheter and that the marker is imageable by the imaging transducer to provide an image that predicts the path on which the penetrator will subsequently advance along with the image of the target location, thereby enabling the operator to rotationally orient the catheter such that that, when the tissue penetrator is subsequently advanced from the catheter, it will extend from the lumen of the blood vessel to the target location. This amended language is quite definite and, when considered in light of the copious written description provided in this application as require by law, is clearly in compliance with the requirements of 35 U.S.C. 112. In particular, the Examiner's attention is directed to Applicant's Figures 6A and 6B as well as the detailed description relating to those figures.

35 U.S.C. §102 Rejections

1. *Yock et al.*

In the Office Action, claims 1-3 were rejected as being anticipated by United States Patent No. 5,724,977 (Yock et al.) on grounds that Yock et al. "teaches a guide catheter 10 advanceable into a blood vessel and a stenotic tissue penetrator 39 (angioplasty catheter of Fig. 8) as well as a rotating imaging transducer fixed to an imaging catheter 38 such that the imaging transducer and the marker (24 or 26) cooperate to enable the operator to rotationally orient the catheter until the until the penetrator path is indicated to be aimed at, for example a stenotic

branch vessel soas (sic) to assure that when the penetrator is advanced it will properly ingress this desired vessel." With reference to the cited Figure 8 of Yock et al. (reproduced below), the system described by Yock et al. comprises three separate catheters, a guide catheter 12, an imaging catheter (not shown in Figure 8) and an atherectomy catheter 39.

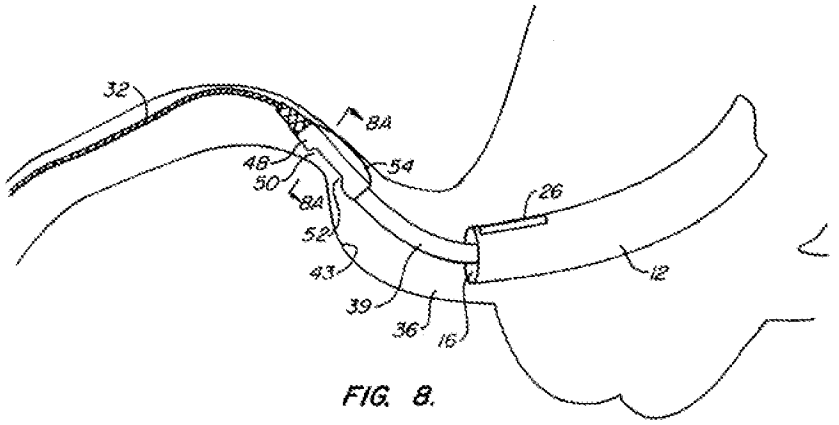

FIG. 8.

Yock et al. specifically describes this three-catheter system as follows:

> Referring to FIG. 8, therapeutic treatment of the coronary artery will be described. After producing the image of FIG. 6B so that the relative orientation of the imaging catheter 38 can be determined (and after aligning the vector 42 with the actual orientation of the strip 26 within the coronary ostium 36 if desired or needed), the imaging catheter 38 is distally advanced beyond the distal end 16 of the catheter body 12 to visualize the coronary artery. The imaging catheter 38 is advanced through the coronary artery until reaching the plaque 46 as shown in FIG. 6D. As the imaging catheter 38 is distally advanced toward the plaque 46, the rotational orientation of the imaging catheter 38 will usually remain virtually unchanged. Hence, the position of the imaging catheter 39 relative to the plaque 46 will be known. Based on the image of the plaque 46 and the image produced as FIG. 6B, the actual orientation of the plaque 46 in the artery can be determined. Once the actual orientation of the plaque is known, the imaging catheter 38 is withdrawn from the coronary artery and an atherectomy catheter 39 is introduced over the guidewire.

> The atherectomy catheter 39 includes a canoe-shaped housing 48 having an aperture 50 therein. Within the aperture 50 is a cutting element 52 which is employed to shave the plaque 46 from the walls of the coronary artery. A balloon 54 is provided on the housing 48 opposite the aperture 50 for forcing the cutting element 52 against the plaque 46 when inflated. When the area having the eccentric plaque 46 is reached under fluoroscopic guidance, the position of the cutter 52 on the atherectomy catheter 39 can be manipulated to ensure that it is facing the eccentric plaque 46, based on the known orientation of the plaque from the previous ultrasound image. If the cutting element 52 is not adjacent the plaque 46, the atherectomy catheter 39 can be rotated from its proximal end (which is outside the patient) to adjust the rotational position of the cutting element 52. When at the proper location, the balloon 54 is inflated and the cutting element 52 is actuated to remove the plaque 46 from the coronary artery. After removal of the plaque 46, imaging of the area can again occur (as illustrated in FIG. 8A) to determine if sufficient plaque 46 has been removed.

In contrast to the two-catheter system described by Yock et al., Applicant's amended claim 1 recites a single catheter device that is useable to penetrate from the lumen of a blood vessel within a patient's body in which the catheter device is positioned to a target location within the patient's body. The device of Applicant's claim 1 comprises: (A) a catheter having a proximal end and a distal end, said catheter being advanceable into said blood vessel; (B) a tissue penetrator that is advanceable in a lateral direction from a side opening in the catheter, said tissue penetrator being operative to penetrate from the lumen of the blood vessel to target location situated outside of the lumen of the blood vessel; (C) an imaging transducer that provides an imaging signal from which an image of the target location and other anatomical structures located adjacent the first blood vessel can be obtained and (D) a marker on the catheter that is imageable by the imaging transducer to provide an image that predicts the path on which the penetrator will subsequently advance along with the image of the target location, thereby enabling the operator to rotationally orient the catheter such that that, when the tissue penetrator is subsequently advanced from the catheter, it will extend from the lumen of the blood vessel to the target location.

The atherectomy catheter 39 of Yock et al. is not a "tissue penetrator" and it is not advanceable "in a lateral direction from a side opening in the catheter" as required by Applicant's amended claim 1. Rather, in the three-catheter system of Yock et al., the guide catheter 12 is

initially advanced to a position where its distal end opening is within the desired coronary artery. A separate imaging catheter is then advanced through the guide catheter 12. As the separate imaging catheter advances out of the distal end of the guide catheter 12, the operator may visualize a reference strip 26 on the guide catheter, thus allowing the rotational orientation of the imaging catheter relative to the guide catheter to be noted. Thereafter, the imaging catheter is removed in its entirety and the atherectomy catheter 39 is inserted in its place. The imaging catheter of Yock et al. clearly does not image any marker that provides an image that predicts the path on which the penetrator will subsequently advance along with an image of the target location, as also required by amended claim 1.

Accordingly, for the above-stated reasons as well as others not expressly articulated here, claims 1-3 are believed to be novel and patentable over Yock et al.

2. Crowley et al.

Also in the Office Action, claims 1-3 were rejected under 35 U.S.C. 102 as being anticipated by United States Patent No. 5,588,432 (Crowley, et al.). Crowley et al. describes an acoustic imaging system for use within the heat. The described system includes a catheter, an ultrasound device incorporated into the catheter, and an electrode mounted on the catheter. The ultrasound device directs ultrasonic signals toward an internal structure in the heart to create an ultrasonic image, and the electrode is arranged for electrical contact with the internal structure. A chemical ablation device mounted on the catheter ablates at least a portion of the internal structure by delivery of fluid to the internal structure. The ablation device includes a material that vibrates in response to electrical excitation, the ablation being at least assisted by vibration of the material. The ablation device may alternatively be a transducer incorporated into the catheter, arranged to convert electrical signals into radiation and to direct the radiation toward the internal structure. The electrode may be a sonolucent structure incorporated into the catheter, through which the ultrasound device is arranged to direct signals. An acoustic marker mounted on the catheter emits a sonic wave when electrically excited. A central processing unit creates a graphical representation of the internal structure, and super-imposes items of data onto the graphical representation at locations that represent the respective plurality of locations within the internal structure corresponding to the plurality of items of data. A display system displays the graphical representation onto which the plurality of items of data are super-imposed.

In the Office Action, the Examiner contends that Crowley et al. discloses two "modes of marker" as follows:

> Two modes of marker are suggested for this system: radioopaque markers 410, 412 as per col. 17 lines 64-65 which serve to define the long axis of the catheter and its general location, and alternatively acoustic marking in the form of PVDF deposition over the ablating electrodes or over generalized portions of the catheter which serve as markings detectable by a separate transesophageal ultrasound probe to serve in a position sensing function to create a wire frame or anatomic image onto display 376 as detailed in cols. 23-24.

Neither of these purported markers constitutes "a marker on the catheter that is imageable by the imaging transducer to provide an image that predicts the path on which the penetrator will subsequently advance along with the image of the target location, thereby enabling the operator to rotationally orient the catheter such that that, when the tissue penetrator is subsequently advanced from the catheter, it will extend from the lumen of the blood vessel to the target location" as recited in Applicant's claim 1. Moreover, the Crowley et al. device is devoid of any "tissue penetrator that is advanceable in a lateral direction from a side opening in the catheter" as recited in Applicant's independent claim 1.

Accordingly, for the above-stated reasons as well as others not expressly articulated here, claims 1-3 are believed to be novel and patentable over Crowley et al.

35 U.S.C. §103 Rejections

Also in the Office Action, all claims were rejected under 35 U.S.C. §103 as being obvious over either Yock et al. or Crowley et al. in view of various secondary references.

Independent claim 1, as presently amended, and all claims depending directly or indirectly from claim 1, are unobvious and patentably distinguishable over Yock et al. and Crowley et al. for the reasons stated above. None of the cited secondary references addresses or makes up for the above-explained shortcomings of Yock et al. or Crowley et al. Thus, amended independent claim 1 and all claims depending directly or indirectly therefrom are unobvious and patentable over all of the cited reference.

Independent claim 13 and the claims that depend directly or indirectly therefrom are also

unobvious over Yock et al., Crowley et al. and all of the cited secondary references taken alone or in combination. Independent claim 13 requires that the catheter device include an exit port on the peripheral wall of the catheter, a penetrator that is advanceable out of the exit port and away from the catheter body on a predetermined penetrator path and a phased array transducer fixedly mounted to the catheter body, such phased array transducer comprising a plurality of transducer elements positioned at circumferentially spaced apart locations and in known circumferential location relative to said exit port to provide an indication of the projected penetrator path along with an image of the target location to enable the operator to rotationally orient the catheter until the target location is aligned with the indication of the projected penetrator path such that when the tissue penetrator is subsequently advanced out of the exit port it will extend into the target location as desired. None of the cited references even remotely suggest this novel combination of elements.

CONCLUSION

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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